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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JULIAN VAN ERLACH, ARLEN L. OLSEN, JEFFREY M. SMITH, LAURA B. SMITH, GERALD E. BENDER, AUDRA L. STINCHCOMB, DENIS P. DONNELLY, MARK D. SCOTT, JAMES E. PETERSON, and ROBERT S. HIRSCH

Appeal 2008-1564
Application 09/727,718
Technology Center 3700

Decided: June 24, 2008

Before DEMETRA J. MILLS, ERIC GRIMES, FRANCISCO C. PRATS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1, 5, 6, 9, and 11-19. The Examiner has rejected the claims as obvious in view of the prior art. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

The Specification discloses "a method for inserting a microdevice or a nanodevice into a body fluid stream" (Spec. 1). The method is said to be

useful for, among other things, "detection, diagnosis, and monitoring of bodily conditions such as myocardial infarctions, stroke, sickle cell anemia, phlebitis and the like" (*id.* at 3).

DISCUSSION

1. CLAIMS

Claims 1 and 15 are representative and read as follows:

1. A method comprising:

providing at least one of a microdevice and a nanodevice, having at least one circuit feature thereon;

introducing by a method selected from the group consisting of reversible osmotic lysis, electroporation, microfine needle injection, and particle gun injection at least one of said microdevice and said nanodevice into at least one cell, wherein said cell is selected from the group consisting of a red blood cell, a liver cell, a nerve cell, a skin cell, a bone cell, a lymph cell, an endocrine cell, a circulatory cell, and a muscle cell.

15. A method comprising:

providing at least one of a nanodevice and a microdevice, having at least one circuit feature thereon;

encapsulating at least one of said microdevice and said nanodevice with non immunogenic polymers, wherein the at least one of said microdevice and said nanodevice is extracellular; and

inserting the at least one of said nanodevice and said microdevice in a blood stream within a body.

2. OBVIOUSNESS I

Claims 1, 5, 6, 9, and 14 stand rejected under 35 U.S.C. § 103 as obvious in view of Benjamin[1] and Berg.[2] Claims 11 and 12 stand rejected under 35 U.S.C. § 103 as obvious in view of Benjamin, Berg, and Østensen.[3] Claim 13 stands stand rejected under 35 U.S.C. § 103 as obvious in view of Benjamin, Berg, Østensen, and Chandrakumar.[4]

The Examiner finds that Benjamin teaches

> a method and system for injecting a microdevice which is encapsulated into a cell (column 15, lines 33-34) into a body. . . . It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure . . . does not preclude the use of other cell types such as red blood cells. The use of a white blood cell is merely an example disclosed by Benjamin et al.

(Answer 3.) The Examiner also finds that it was "known to encapsulate something into a cell through methods such as osmotic lysis or electroporation as disclosed for example by Berg et al (column 1, lines 8-20)" (*id.*). The Examiner concludes that it would have been obvious to modify Benjamin's method by introducing the microdevice using the methods taught by Berg: "Such a modification merely involves the selection of one well known method for providing for cell encapsulation of a substance" (*id.*)

We agree with the Examiner's reasoning and conclusion.

Appellants argue that

> encapsulation of a foreign object by a white blood cell is due to that cell type's inherent phagocytic nature; a characteristic not

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[1] Benjamin et al., U.S. Patent 4,793,825, issued Dec. 27, 1988.
[2] Berg et al., U.S. Patent 5,876,989, issued March 2, 1999.
[3] Østensen et al., U.S. Patent 6,375,931 B2, issued April 23, 2002.
[4] Chandrakumar et al., U.S. Patent 6,472,874, issued Oct. 29, 2002.

> common to all cell types. Appellants therefore assert that the Examiner does not teach or suggest a motivation to look to [Berg] to encapsulate a device by a cell type other than a white blood cell . . . because [Berg] only teaches "introducing molecules into the cytosol of living cells using means other than encapsulation."

(Br. 5.)

This argument is not persuasive. Benjamin discloses a microdevice (Benjamin, col. 1, ll. 41-52) that "may be encapsulated in a cell, e.g. a white cell. This may be achieved by allowing white cells to engulf the device in vitro and to inject the resultant white cells and devices. Since the body sees the white cells as friendly the devices are not trapped." (*id.* at col. 15, ll. 33-37.) That is, Benjamin teaches encapsulating the device in a cell that the patient's body will recognize as "self" rather than "foreign," in order to prolong its useful lifetime *in vivo*.

Benjamin specifically states that a white blood cell is only an example of the types of cell that can be used to encapsulate the disclosed microdevice. Those skilled in the art would therefore have understood that other cell types would also serve the purpose of masking the microdevice from the patient's immune system. Those skilled in the art would also have understood from Berg that microinjection and electroporation were "[a]mong the most commonly used methods" for introducing extracellular material into the cytosol of living cells (Berg, col. 1, ll. 9-15).

We agree with the Examiner that it would have been obvious to one of ordinary skill in the art to use the techniques disclosed by Berg to introduce Benjamin's microdevice into a cell, either a white blood cell or another cell type. We note that a white blood cell would reasonably seem to be a

"circulatory cell," as recited in claim 1. We affirm the rejection of claim 1 as obvious in view of Benjamin and Berg. Claims 5, 6, 9, and 14 fall with claim 1 because they were not argued separately. 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner also rejected claims 11-13 as obvious in view of Benjamin and Berg, combined with other references. Appellants do not dispute that Østensen and Chandrakumar, combined with Benjamin and Berg, would have suggested the additional limitations of claims 11-13 (Br. 6). We therefore affirm the rejection of claims 11 and 12 as obvious in view of Benjamin, Berg, and Østensen, and the rejection of claim 13 as obvious in view of Benjamin, Berg, Østensen, and Chandrakumar.

3. OBVIOUSNESS II

Claim 15 stands rejected under 35 U.S.C. § 103 as obvious in view of Benjamin and Jacobs.[5] Claim 16 stands rejected under 35 U.S.C. § 103 as obvious in view of Benjamin, Jacobs, and Schechter.[6] Claims 17-19 stand rejected under 35 U.S.C. § 103 as obvious in view of Benjamin and either of Dustin[7] or Li.[8]

The Examiner relies on Benjamin for the teachings previously discussed, and finds that it was "well known in the art to use nonimmunogenic polymers to enhance retention of [an] implanted device by inhibiting immune recognition thereof. An example is seen in Jacobs et al." (Answer 4). The Examiner concludes that "it would have been obvious to one skilled in the art to have encapsulated the device in a nonimmunogenic

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[5] Jacobs et al., WO 97/10847, published March 27, 1997.
[6] Schechter, U.S. Patent 4,120,649, issued Oct. 17, 1978.
[7] Dustin et al., U.S. Patent 5,071,964, issued Dec. 10, 1991.
[8] Li et al., U.S. Patent 6,090,408, issued July 18, 2000.

polymer[ ] in order to enhance vascular retention and prevent/diminish phagocytosis, endocytosis, or immune complex-mediated clearance" (*id.*).

We agree with the Examiner's reasoning and conclusion.

Appellants argue that Benjamin "merely teaches 'coating with an antibody,' which is not a non immunogenic polymer" and that "the Examiner does not teach or suggest the motivation by which a person skilled in the art would modify the coating of a device with antibody as in [Benjamin] by Jacobs et al." (Br. 7).

This argument is not persuasive. Benjamin discloses coating its microdevice with antibodies in order to target the microdevice to particular cells such as tumor cells or bacteria (Benjamin, col. 3, ll. 22-25 and 39-40). The antibody coating is not disclosed as useful for shielding the microdevice from the immune system; that function is performed in Benjamin by encapsulating the microdevice in a cell (see *id.* at col. 15, ll. 33-37). Jacobs teaches that coating antibodies with "a nonimmunogenic hydrophilic polymer that provides a hydration shell around the monoclonal antibody . . . inhibit[s] immune recognition thereof" (Jacobs 10: 36 to 11: 2). Jacobs also teaches that a preferred polymer is polyethylene glycol (*id.* at 11: 3).

We agree with the Examiner that it would have been obvious to one of ordinary skill in the art to substitute the coating of a nonimmunogenic hydrophilic polymer (e.g., polyethylene glycol) taught by Jacobs for the cell-encapsulation taught by Benjamin because both methods were taught by the prior art to provide the same function – inhibiting recognition of a foreign substance by a patient's immune system. We affirm the rejection of claim 15 as obvious in view of Benjamin and Jacobs.

The Examiner also rejected claim 16 as obvious in view of Benjamin, Jacobs and Schechter, and rejected claims 17-19 as obvious in view of Benjamin and either Dustin or Li. Appellants do not dispute that Schechter, combined with Benjamin and Jacobs would have suggested the additional limitations of claim 16, or that either of Dustin or Li, combined with Benjamin, would have suggested the limitations of claims 17-19 (Br. 7). We therefore affirm the rejections of claims 16-19.

SUMMARY

We affirm all of the rejections on appeal.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

dm

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